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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,210	11/21/2005	Pierre Ducray	H-32531A	5227

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Novartis Animal Health US Inc.
3200 Northline Avenue, Suite 300
Greensboro, NC 27408

EXAMINER

POWERS, FIONA

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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02/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,210	Applicant(s) DUCRAY ET AL.	
	Examiner Fiona T. Powers	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 40-50 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7, 9-28, 31 and 32 is/are allowed.
- 6) ☒ Claim(s) 34, 35, 40 to 47 is/are rejected.
- 7) ☒ Claim(s) 8, 29, 30, 33 and 48 to 50 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/16/04</u> . | 6) <input type="checkbox"/> Other: ____ |

Receipt is acknowledged of the information disclosure statement and preliminary amendment filed December 16, 2004, which have been entered in the file.

Claims 46 and 48 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 46 and 48 have not been further treated on the merits.

Claims 8, 29, 30 and 33 are objected to because of the following informalities: in claim 8, line 4 and claim 29, page 8, line 10 "Alkoxy" should be -alkoxy--. Claim 30 contains a period within the claim. The period on line 10 should be replaced with a semicolon. In claim 33, "prepatation" should be -preparation--. Appropriate correction is required.

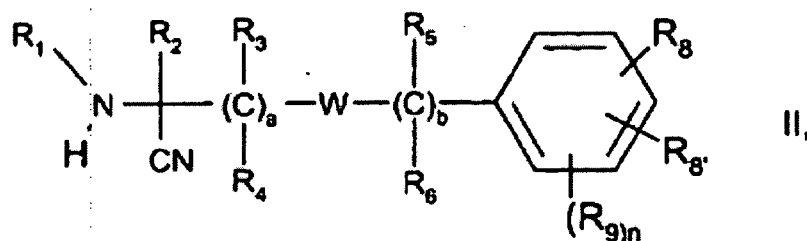
The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

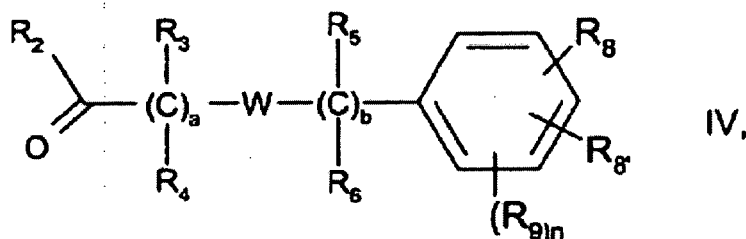
Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art

to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 34 claims a process for the preparation of a compound of the formula II



by reacting a compound of the formula IV



with an inorganic or organic cyanide and with a compound of formula R_6-NH_2 . However, the compound of the formula II in which R_1 is bonded to the amino group would not be produced by this process. The compound that would be produced would have R_6 bonded to the amino group.

Claims 35 and 40 to 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method treating an animal for endo- and ecto-parasites and compositions for controlling endo- and ecto-parasites, does not

reasonably provide enablement for a method of controlling all parasites or treating an animal for all parasites and compositions for controlling all parasites. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph are as follows:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of skill in the art.

See *In re Wands*, 8 USPQ2d 1400.

In the instant case, there is unpredictability in the art and the breadth of the claims encompasses a method of controlling all parasites, treating an animal for all parasites and compositions for controlling all parasites. The disclosure

(pages 39 to 41) only directs one to a method of treating Mongolian gerbils for *Trichostrongylus colubriformis* and *Haemonchus contortus* and other tests which may be performed to determine insecticidal and/or acaricidal activity of the compounds of formula I. An undue amount of experimentation is needed to determine which compounds are effective for a method of controlling all parasites, treating an animal for all parasites and compositions for controlling all parasites. While the specification describes a method of treating Mongolian gerbils for *Trichostrongylus colubriformis* and *Haemonchus contortus* there is no correlation between compounds which have this activity and a method of controlling all parasites, treating an animal for all parasites and compositions for controlling all parasites.

To overcome this rejection, claims 35 and 46 should be amended to recite "endo- and ecto-parasites" instead of "parasites" and claims 40 to 45 should be canceled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and

distinctly claim the subject matter which applicant regards as the invention.

Claim 34 claims a process for the preparation of compounds of the formula II according to claim 2. However, compounds of the formula II are not described in claim 2.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by Wawzonek et al. (Organic Preparations and Procedures International, 5(6), 265-269, 1973) and March (Advanced Organic Chemistry, 3rd Edition, 855-856, 1985), cited.

Wawzonek et al. disclose the claimed process for the preparation of a compound of the formula II wherein R₁, R₂, R₃ and R₄ are hydrogen, W is O, R₅ is phenylalkoxy (Ph-CH₂-O-), R₆ is hydrogen, and a, b and n are 0 by the Strecker reaction which March discloses is the reaction of an aldehyde which is the corresponding compound of the formula IV in which R₂ is hydrogen with an inorganic cyanide and an amine. Note Compound No. 3 on

page 265 and the first paragraph on page 266 of Wawzonek et al.
and Section 6-50 on page 855 and 856 of March.

The references made of record and not relied upon show the
state of the art. The references that are crossed out on PTO
1449 are not of record in the file.

Claims 49 and 50 are objected to as being dependent upon a
rejected base claim, but would be allowable if rewritten in
independent form including all of the limitations of the base
claim and any intervening claims.

Claims 1 to 7, 9 to 28, 31 and 32 are allowed.

Any inquiry concerning this communication or earlier
communications from the examiner should be directed to Fiona T.
Powers whose telephone number is 571-272-0702. The examiner can
normally be reached on Monday - Friday 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are
unsuccessful, the examiner's supervisor, Joseph K. McKane can be
reached on 571-272-0699. The fax phone number for the
organization where this application or proceeding is assigned is
571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fiona T. Powers
Fiona T. Powers
Primary Examiner
Art Unit 1626

ftp
January 31, 2008